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United States District Court,E.D. Pennsylvania.

In re: **VICURON** PHARMACEUTICALS, INC. SECURITIES LITIGATION

No. Civ.A. 04-2627.

July 1, 2005.

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MEMORANDUM

BARTLE, J.

***1** Plaintiff shareholders in this putative securities class action have sued Vicuron Pharmaceuticals, Inc. ("Vicuron") [FN1] and certain of its officers and directors [FN2] pursuant to: § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated under § 10(b) of the Exchange Act, 17 C.F.R. § 240.10b-5; § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a); and § 11 of the Securities Act of 1933 ("Securities Act"), 15 U.S.C. § 77k.

FN1. Vicuron was known as Versicor, Inc. until March, 2003, when it changed its name as a result of its merger with Biosearch Italia.

FN2. As described in the amended complaint, the officers and directors named are:

• George F. Horner III, President and Chief Executive Officer and a Director, and Dov A. Goldstein, Chief Financial Officer. These defendants were responsible for communications to the investment community and knew the material, adverse non-public information about anidulafungin, the New Drug Application ("NDA") for EC indication and the clinical studies alleged from corporate documents, including the company's regulatory submissions to the Food and Drug Administration ("FDA") prior to and during the class period, and oral and written communications with other corporate officers and employees. Am. Compl. ¶ 12(a) & (b).

• Timothy J. Henkel, Chief Medical Officer. Dr. Henkel also personally conducted the company's communications to the investment community and to the FDA concerning anidulafungin clinical studies, the NDA submission, and subsequent amendments and was therefore fully informed of the pharmacological profile of the drug as well as the design and results of the clinical studies. *Id.* ¶ 12(c). We refer to the defendants described in ¶ 12, *i.e.*, Messrs. Horner, and Goldstein and Dr. Henkel as the "officer defendants."

• Claudio Quarta, Chief Operating Officer and Director. Mr. Quarta was CEO of Biosearch Italia prior to its merger with Versicor, Vicuron's predecessor, in 2003. *Id.* ¶ 13(a).

• David V. Mulligan, Chairman of Board of Directors and member of the scientific advisory board of Vicuron. *Id.* ¶ 13(b).

• Christopher T. Walsh, James H. Cavanaugh, Costantino Ambrosio, Ubaldo Livolsi, and Francesco Parenti were members of the Board of Directors. *Id.* ¶ 13.

• The defendants described in ¶ 13 of the amended complaint, and defendant

> Goldstein, shall be referred to as the "director defendants." As stated in ¶ 14 of the amended complaint, each of these defendants signed the allegedly false and misleading Registration Statement pursuant to the secondary offering of stock in July, 2003. *Id.* ¶ 14.

Before the court are two motions. Defendants have moved to dismiss the amended complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiffs subsequently moved to strike a number of the exhibits related to defendants' motion to dismiss.

The amended complaint alleges that defendants made numerous materially false and misleading statements concerning anidulafungin, Vicuron's lead product in development for the treatment of esophageal candidiasis ("EC"). EC is an infection of the esophagus caused by an overgrowth of a fungus called Candida, which normally exists in the human body and only causes problems when there is an overgrowth. In essence, defendants argue that the amended complaint does not allege fraud with sufficient particularity, that defendants' statements are protected under the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4 *et seq.*, and that no claims are stated under the other referenced securities statutes.

Plaintiffs aver that defendants' misrepresentations during the class period of January 6, 2003 to May 24, 2004 resulted in the artificial inflation of Vicuron's common stock to a high of $23.90 per share. According to the amended complaint, this artificial increase allowed Vicuron to complete a merger with Biosearch Italia in March, 2003 by using 21.4 million shares of Vicuron stock as currency for the transaction. Vicuron was also purportedly able to complete a secondary offering of six million shares in July, 2003 for net proceeds of $83 million.

On May 24, 2004, Vicuron announced that the United States Food and Drug Administration ("FDA") had found that the company's new drug application ("NDA") for anidulafungin did not support its proposed labeling for the product. Vicuron reported that the application was still "approvable," that is, that anidulafungin might eventually be approved with additional clinical data or studies. However, it noted that the FDA had serious concerns about the drug's relapse rates, that is how quickly EC reappeared in patients treated with anidulafungin as compared with another EC drug called fluconazole. [FN3] At this news, the price of Vicuron stock sharply decreased to $13.04 per share, a loss of more than 40 percent from the previous day. The value of that stock subsequently fell to below $10.00 per share.

> FN3. The claims in the present action discuss comparisons made between anidulafungin and two other drugs already on the market for the treatment of EC: fluconazole, a drug marketed by Pfizer as "Diflucan;" and caspofungin, a drug marketed by Merck as "Caspofungin."

I.

Under Rule 12(b)(6), a claim should be dismissed only where "it appears beyond doubt that plaintiff[s] can prove no set of facts in support of [their] claim which would entitle [them] to relief." *In re Rockefeller Ctr. Props., Inc. Sec. Litig. ("Rockefeller")*, 311 F.3d 198, 215 (3d Cir.2002). All well-pleaded allegations in the complaint must be accepted as true, and all reasonable inferences are drawn in favor of the non-moving party. *Id.* We may consider "the allegations contained in the complaint, exhibits attached thereto, and matters of public record." *Beverly Enterprises, Inc. v. Trump*, 182 F.3d 183, 190 n. 3 (3d Cir.1999); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir.1993).

***2** In deciding a motion to dismiss, a court also may consider "document[s] *integral to or explicitly relied* upon in the complaint ... without converting the motion [to dismiss] into one for summary judgment." *In re Burlington Coat Factory Sec. Litig. ("Burlington Coat Factory")*, 114 F.3d 1410, 1426 (3d Cir.1997) (emphasis in original) (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir.1996)). Consideration of such documents is permitted to prevent a plaintiff from maintaining a claim based on a statement or provision taken out of context when consideration of the full context may be necessary. *Id.* Defendants do not argue that the court must accept these exhibits for their truth, and we will not do so.

Additionally, it is well-settled that a court may take judicial notice of documents filed with the SEC but not relied upon in the complaint, SEC filings and press releases explicitly relied upon in the complaint, and records concerning stock prices. *See In re NAHC, Inc. Sec. Litig. ("NAHC II")*, 306 F.3d 1314, 1331 (3d Cir.2002). *See also* Fed.R.Evid. 201. Matters of

public record, such as press releases and statements filed with the SEC may not be considered for their truth, but only to determine what was said. *See In re NACH, Inc. Sec. Litig.* (*"NAHC I"*), No. CIV.A. 00-4020, 2001 WL 1241007, *5 (E.D.Pa.2001), *aff'd,* 306 F.3d 1314 (3d Cir.2002); *Oran v. Stafford,* 226 F.3d 275, 289 (3d Cir.2000) (citing *Kramer v. Time Warner, Inc.,* 937 F.2d 767, 774 (2d Cir.1991)); *In re Viropharma, Inc. Sec. Litig.,* No. CIV.A. 02-1627, 2003 WL 1824914, *1 (E.D.Pa. Apr.7, 2003).

Because this is an action for securities fraud, we must take into account Rule 9(b) of the Federal Rules of Civil Procedure in deciding this motion to dismiss. *See Cal. Pub. Employees' Retirement Sys. v. Chubb Corp.,* 394 F.3d 126, 144 (3d Cir.2004). Rule 9(b) provides that the "[i]n all averments of fraud or mistake, circumstances constituting fraud or mistake shall be stated with particularity." Fed.R.Civ.P. 9(b). The Court of Appeals of this Circuit has held that "Rule 9(b) requires a plaintiff to plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage." *Shapiro v. UJB Fin. Corp.,* 964 F.2d 272, 284 (3d Cir.1992), *cert. denied,* 506 U.S. 934, 113 S.Ct. 365, 121 L.Ed.2d 278 (1992). *See also Cal. Pub. Employees' Retirement Sys.,* 394 F.3d at 161-62.

In addition to the requirements of Rule 9(b), the PSLRA "imposes another layer of factual particularity to allegations of securities fraud." *GSC Partners CDO Fund v. Washington* (*"GSC Partners*), 368 F.3d 228, 236-37 (3d Cir.2004) (citing *Rockefeller,* 311 F.3d at 217). The PSLRA requires that the complaint set forth "each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1); *GSC Partners,* 368 F.3d at 237. In essence, the complaint must state "the essential factual background that would accompany 'the first paragraph of any newspaper story'-that is, the 'who, what, when, where, and how' of the events at issue.' " *GSC Partners,* 368 F.3d at 239 (citing *Burlington Coat Factory,* 114 F.3d at 1422).

II.

***3** As a preliminary matter, we will address plaintiffs' motion to strike a number of exhibits submitted by defendants in support of their motion to dismiss.

Exhibit 7 attached to defendants' memorandum of law in support of the motion to dismiss contains excerpts discussing the technical term "volume of distribution" from two reference materials: David E. Golan, et al., *Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy,* 33, 39 (2005); and Mark H. Beers, M.D. and Robert Berkow, M.D., *The Merck Manual of Diagnosis and Therapy* 2561 (17th ed.1999). [FN4] Plaintiffs do not dispute the accuracy of the reference texts or the definitional information. Thus, we will take judicial notice of Exhibit 7. *See* Fed.R.Evid. 201; *Werner v. Werner,* 267 F.3d 288, 295 (3d Cir.2001).

FN4. Defendants have requested that this court take judicial notice of Exhibits 1 through 8 to their motion to dismiss, consisting of definitions from Webster's Medical Dictionary and portions of two reference materials. Exhibits 1 through 6 and Exhibit 8 are definitions of medical terms taken from Webster's Medical Dictionary to which plaintiffs do not object.

Exhibits, A, [FN5] B, [FN6] D, [FN7] E, [FN8] J, [FN9] L, [FN10] M, [FN11] P, [FN12] and Q [FN13] were attached to the "declaration of Marc S. Williams in support of motion to dismiss amended complaint." Defendants maintain they have proffered these exhibits in order "to provide the Court with the full text or relevant excerpts of the SEC statements, press releases and other documents quoted or referenced by plaintiffs in the Amended Complaint." Williams Decl. ¶ 2. All of these exhibits were quoted in part in the amended complaint. As explained above, the court may consider any document in its entirety when a portion is explicitly relied upon in the complaint. *Burlington Coat Factory,* 114 F.3d at 1426.

FN5. Exhibit A is a copy of the FDA approved product labeling for caspofungin, or Cancidas, as it appears on the website of Merck & Co., Inc. *See* Am. Compl. ¶ 28.

FN6. Exhibit B is a copy of excerpts from Vicuron's Amendment No. 3 to Registration Statement of November 5, 2002. *See* Am. Compl. ¶ 30.

FN7. Exhibit D is a press release of March

17, 2003 referred to in the amended complaint at ¶ 37.

FN8. Exhibit E is a transcript of a conference call of March 17, 2003 between officers of Vicuron and market analysts. Am. Compl. ¶ 38.

FN9. Exhibit J is a copy of excerpts from Vicuron's Prospectus Supplement of July 17, 2003. *Id.* ¶ 48.

FN10. Exhibit L is a copy of excerpts from Vicuron's Amended Annual Report for the period ending December 31, 2002, referred to in the amended complaint ¶ 49.

FN11. Exhibit M is a copy of excerpts from Vicuron's Annual Report for the period ending December 31, 2003, referred to in the amended complaint ¶ 57.

FN12. Exhibit P is a copy of a publication of September 15, 2004 by David S. Krause published in *Clinical Infectious Diseases*. *See* Am. Compl. ¶ 60.

FN13. Exhibit Q is a copy of an analyst report by Eun Yang, Ph.D., referred to in ¶ 65 of the amended complaint.

Accordingly, the motion of plaintiffs to strike exhibits will be denied.

III.

We now turn to the motion of defendants to dismiss under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

The basic elements of a securities fraud claim pursuant to Rule 10b-5 under § 10(b) of the Exchange Act are: (1) a material misrepresentation (or omission); (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance, or "transaction causation"; (5) economic loss; and (6) loss causation. *Dura Pharm., Inc. v. Broudo*, 544 U.S. ----, 125 S.Ct. 1627, 1631, 161 L.Ed.2d 577 (2005). Defendants' motion to dismiss contests only the elements of material misrepresentation or omission, scienter, and loss causation.

A. Material Misrepresentations or Omissions and Scienter

Therefore, we must first determine whether plaintiffs' amended complaint has sufficiently pleaded any material misrepresentation or omission under Rule 10b-5. Certain misrepresentations and omissions are not actionable. It is well established that "vague and general statements of optimism 'constitute no more than puffery and are understood by reasonable investors as such.' " *In re Advanta Corp. Sec. Litig. ("Advanta")*, 180 F.3d 525, 538 (3d Cir.1999) (citing *Burlington Coat Factory*, 114 F.3d at 1428 n. 14). "Such statements, even if arguably misleading, do not give rise to a federal securities claim because they are not material: there is no 'substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.' " *Id.* (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449, 96 S.Ct. 2126, 48 L.Ed.2d 757 (1976)). Misrepresentations or omissions that are "so *obviously unimportant* to an investor that reasonable minds cannot differ on the question of materiality" are inactionable as a matter of law. *In re Adams Golf, Inc. Sec. Litig. ("Adams Golf")*, 381 F.3d 267, 275 (3d Cir.2004) (citing *Shapiro*, 964 F.2d at 281 n. 11).

***4** Second, the PSLRA creates a safe harbor against claims of material misrepresentation or omission for certain forward-looking statements. [FN14] *See* 15 U.S.C. § § 77z-2(c), 78u-5(c). Under the PSLRA, there is no liability "based on an untrue statement of a material fact or omission of a material fact necessary to make the statement not misleading" if and to the extent that the forward-looking statement is:

FN14. The PSLRA defines a forward-looking statement as:
(A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
(B) a statement of the plans or objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
(C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to

> the rules and regulations of the Commission;
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);
> (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
> (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.
> 15 U.S.C. § § 77z-2(i)(1), 78u-5(i)(1).

(i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or
(ii) immaterial

unless plaintiff proves the statement:(i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
(ii) if made by a business entity; was
(I) made by or with the approval of an executive officer of that entity; and
(II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

15 U.S.C. § § 77z-2(c), 78u-5(c). Thus, there can be liability for an untrue statement of material fact or omission of a material fact necessary to make the statement not misleading if the statement is material and: (1) the statement is not identified as a forward-looking statement and accompanied by meaningful cautionary statements; (2) plaintiff can prove a person made the statement with actual knowledge that it was false or misleading; or (3) plaintiff can prove a business entity executive officer made or approved the statement with actual knowledge that it was false or misleading. More simply, a forward-looking statement identified as such and with the appropriate cautionary language "is shielded by the safe-harbor provision unless the plaintiff proves it was made with 'actual knowledge ... that the statement was false or misleading.' " *Advanta,* 180 F.3d at 535. Accordingly, an allegation of a misrepresentation or omission must be material and, if it is forward-looking, must overcome the safe harbor protection of the PSLRA in order to survive dismissal.

To withstand a motion to dismiss their Rule 10b-5 claim, plaintiffs must also plead with particularity facts giving rise to a "strong inference" of scienter as to each act or omission. *GSC Partners,* 368 F.3d at 237 (citing 15 U.S.C. § 78u-4(b)(2)). "Scienter" has been defined by our Court of Appeals as "a mental state embracing intent to deceive, manipulate or defraud, or, at a minimum, highly unreasonable (conduct), involving not merely simple, or even excusable negligence, but an extreme departure from the standards of ordinary care, ... which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *In re Alpharma Inc. Sec. Litig. ("Alpharma"),* 372 F.3d 137, 148 (3d Cir.2004) (citing *In re Ikon Office Solutions, Inc.,* 277 F.3d 658, 667 (3d Cir.2002)). This "strong inference" of scienter supersedes the provision of Rule 9(b) allowing state of mind to be averred generally. *GSC Partners,* 368 F.3d at 237. It may be set forth "either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Burlington Coat Factory,* 114 F.3d at 1418; *GSC Partners,* 368 F.3d at 237.

***5** Thus, with regard to scienter, plaintiffs have two options in their pleading. First, they may state with particularity facts giving rise to a strong inference of motive and "assert a concrete and personal benefit to the individual defendants resulting from this fraud." *Alpharma,* 372 F.3d 149; *GSC Partners,* 368 F.3d at 237. Alternatively, plaintiffs may allege facts concerning recklessness. *See GSC Partners,* 368 F.3d at 237; *Alpharma,* 372 F.3d at 148. It is not enough simply to allege that the individual defendants knew or must have known a statement was false or misleading solely because of their positions within the company. However, allegations that key officers and directors knew or must have known of false or misleading statements because the statements involved the company's lead product will satisfy the pleading requirements of scienter. *Advanta,* 180 F.3d at 539 (citing *In re Ancor Communications, Inc. Sec. Litig.,* 22 F.Supp.2d 999 (D.Minn.1998)).

Because the material misrepresentation or omission and scienter elements of a Rule 10b-5 claim are related, we will examine whether they have been properly pleaded as to each statement cited by plaintiffs in their amended complaint. The amended complaint alleges that each of the defendants, with knowledge or reckless disregard for the truth,

disseminated or approved the statements claimed by plaintiffs to be materially false. Am. Compl. ¶ 68.

1. January 6, 2003 Press Release [FN15]

FN15. In the amended complaint, plaintiffs have emphasized certain text of excerpted portions in bold and italicized lettering. We interpret the distinction to indicate that the emphasized portions are what plaintiffs claim to be actionable. We will read the plain text portions as simply context for the emphasized portions.

Plaintiffs first allege that part of Vicuron's press release of January 6, 2003 [FN16] was materially false or misleading. According to the amended complaint, defendants falsely compared the potency of anidulafungin to that of amphotericin B, which defendants knew to be "one of the most potent antifungal agents available." Am. Compl. ¶ 34. Plaintiffs also claim that any comparison to amphotericin B was irrelevant to the approvability or marketing of a drug that could be used for treating EC. Additionally, plaintiffs allege that defendants had no in vivo, that is, clinical data to support their misleading claim that anidulafungin was superior to the drug fluconazole with regard to relapse rates. [FN17] *Id.* ¶ ¶ 6, 35. According to plaintiffs, defendants' claims about the potency of anidulafungin could only have been validated through a clinical study or by observing highly favorable relapse rates in the Phase III study. [FN18] *Id.*

FN16. *January 6, 2003 Press Release:* (as excerpted by plaintiffs)
NDA Filing
Versicor [Vicuron] is also evaluating anidulafungin in a Phase III trial for the treatment of EC, a serious fungal infection of the esophagus. The company expects to announce results of this trial in the first quarter of 2003 and, based on these results, file a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) by the end of April 2003....
"We are making excellent progress with anidulafungin, the first of three promising advanced stage product candidates we and our proposed merger partner, Biosearch Italia, are working to commercialize around the world over the next few years," said George F. Horner III, president and chief executive officer of Versicor [Vicuron]. *"Anidulafungin belongs to the echinocandin class, the first new class of antifungal agents in 40 years, which promises to revolutionize the treatment of fungal infections. Drugs in this class are distinct due to their fungicidal activity, ability to treat a broad range of fungi, low potential for development of resistance and possibly more favorable safety profile. We believe these attributes will help us differentiate anidulafungin from other agents currently used to treat serious hospital fungal infections."*
About Anidulafungin
Anidulafungin is a naturally occurring molecule that has been significantly improved through chemical modification. *In vitro studies have demonstrated that anidulafungin combines both the potency and killing effects of the polyene class (e.g., amphotericin B) without the resistance problems found with the azole class (e.g.fluconazole). Anidulafungin is a broad-spectrum agent, and has been demonstrated to be highly potent in vitro against the fungi responsible for serious systemic infections. Preclinical studies have shown that five-minute exposure to anidulafungin in vitro kills more than 99 percent of Candida, including fluconazole-resistant strains.* Anidulafungin has no cross-resistance with azoles or amphotericin, and in the laboratory it has proven very difficult to develop resistance to anidulafungin. Anidulafungin also was well tolerated in the Phase I study when given in combination with cyclosporine, the leading chronic immunosuppressive drug.
(Emphasis in original.)

FN17. In vivo means within a living organism. In vitro means in a test tube or outside a living organism.

FN18. As stated in the amended complaint, the developing and marketing approval process of a new drug has several phases:
Phase I The FDA requires tests involving human subjects to study the drug's safety profile and safe dosage, absorption, distribution, and metabolization of the drug in the body, and duration of action.
Phase II Controlled trials of volunteer

> patients with the relevant disease assess effectiveness.
> Phase III This phase usually involves patients in clinics and hospitals who are closely monitored by physicians to confirm efficacy and identify adverse events.
> NDA Submission and Review-FDA disciplinary review of contents of application for marketing approval to determine whether the clinical trial and other data demonstrate effectiveness for intended use and whether the established benefits outweigh known risks.
> Am. Compl. ¶ 21.

The alleged misrepresentations and omissions at issue in this statement are material. The first portion describes the characteristics of the echinocandin class and represents that anidulafungin, as part of that class, will be a revolutionary drug. In the second portion, defendants specifically discuss characteristics of anidulafungin and comparisons between it and fluconazole. These types of descriptions are important to investors.

Defendants contend that the press release was a protected forward-looking statement. We agree, in part. The first portion of this press release, which concerns a future NDA filing, is forward-looking. It is accompanied by meaningful cautionary language, which states that the projections are subject to change for a variety of reasons. The allegations of actual knowledge of the press release's falsity are not pleaded with sufficient particularity as to the statements regarding the future NDA filing. Therefore, the section of the January 6, 2003 press release concerning the NDA filing is protected by the safe harbor of the PSLRA for forward-looking statements.

***6** However, we disagree that this press release was entirely forward-looking. The portion designated "About Anidulafungin" discusses past studies and their results. This portion is not protected under the PSLRA's safe harbor.

Plaintiffs have asserted enough to raise a "strong inference" of fraud as to this portion of the January 6, 2003 press release. The amended complaint states among other things that defendants had studied the marketplace and were well aware of the advantages and disadvantages of anidulafungin in relation to other antifungal agents and that defendants were aware of data which were concealed or not disclosed. *Id.* ¶ 20. In addition, anidulafungin was Vicuron's lead product in development, and it is reasonable to infer the defendants knew the relevant facts about this drug. *Advanta*, 180 F.3d at 539. We find plaintiffs have sufficiently pleaded scienter as to the January 6, 2003 press release.

The amended complaint, except as noted above, meets the standards of particularity under Rule 9(b) and the PSLRA with respect to this press release.

2. March 17, 2003 Press Release

Plaintiffs further allege that Vicuron's March 17, 2003 press release [FN19] was materially false or misleading. As stated in the amended complaint, defendants denied the problematic implications of the relapse rates, measured at the day 14 post-treatment endpoint. [FN20] Am. Compl. ¶ 39. Plaintiffs allege that defendant Henkel knew that the day 14 post-treatment endpoint was important for a determination of efficacy. *Id.* While any difference in the relapse rates between caspofungin and fluconazole, drugs already on the market to treat EC, were not statistically significant, anidulafungin purportedly was inferior to these drugs with regard to relapse rates, and defendants' alleged minimization of that comparison was materially misleading. *Id.* ¶ 7(f). The amended complaint also states defendants were aware that disclosing the relevance of the relapse rate data would inform investors of the underlying problems with Vicuron's Phase III study of anidulafungin and would diminish chances for FDA approval. *Id.* ¶ ¶ 7, 20. Further, the amended complaint alleges that contrary to Henkel's statement in the press release, there was no standard practice calling for the use of follow-up prophylactic therapy in the treatment of EC. *Id.* ¶ 39.

> FN19. *March 17, 2003 Press Release:* (as excerpted by plaintiffs)
> Veriscor Inc. today announced positive results from a pivotal Phase III clinical trial with the company's lead investigational product candidate, anidulafungin, an anti-fungal agent, and reiterated its intention to file a New Drug Application for anidulafungin with the United States Food and Drug Administration (FDA) by the end of April this year.
> *The trial showed that anidulafungin is as effective as fluconazole,* the standard-of-care for the treatment of esophageal candidiasis, a painful and debilitating fungal infection of

the esophagus that commonly affects patients with compromised immune systems. Anidulafungin belongs to the first new class of anti-fungal agents, called echinocandins, introduced in more than 40 years.

"That the primary endpoint in this study was fulfilled marks an important benchmark for the development of anidulafungin," said Dr. Thomas J. Walsh, co-author on the study and Senior Investigator at the National Cancer Institute and Chief of the Immunocompromised Host Section. *"This large clinical trial demonstrates proof of principle that this echinocandin is comparable to fluconazole in treatment of esophageal candidiasis in humans."* Dr. Walsh further observed, *"The data are consistent with our preclinical studies demonstrating the safety and efficacy of anidulafungin in experimental esophageal candidiasis.* The new class of echinocandins offers broad-spectrum alternatives in the treatment of invasive fungal infections that include candidiasis and aspergillosis. *Compounds within this class have low potential for emergence of resistance, an excellent safety profile,* and minimal drug-drug interactions. Anidulafungin promises to be an important addition to our current antifungal armamentarium for treatment of invasive fungal infections in seriously ill patients."

"This data, along with positive data from the previous trials, will form the basis of what we believe will be a strong NDA submission to the FDA," said Timothy J. Henkel, M.D., Ph.D., Versicor's [Vicuron's] chief medical officer.

The NDA submission will include data from the Phase III esophageal candidiasis trial; data from a previously reported Phase II study in invasive candidemia/candidiasis, the most common hospital-based fungal infection with high mortality rates; and interim safety data from an ongoing Phase III trial studying anidulafungin in aspergillosis, another serious, opportunistic fungal infection with high mortality rates.

"Both treatments proved highly effective at the end of therapy based on endoscopic response, the most objective measure, as well as clinical and mycological responses, which were secondary endpoints," added Dr. Henkel. "End-of-therapy response, rather than follow-up, is most significant in this disease because almost all patients eventually relapse. *As expected in this trial population, relapse rates in both groups were substantial. However, this has little clinical relevance because current clinical guidelines and standard practice call for follow-up prophylactic therapy."*

FN20. The Phase III two-week or day 14 post-treatment endpoint is the point at which the relapse rates at issue were measured.

The alleged misrepresentations in this press release are material to investors. Further, we find that the statements identified in this press release cannot be construed as forward-looking. These portions identified in the amended complaint discuss almost exclusively the studies and comparisons between anidulafungin and other drugs, including existing data supporting a supposedly strong NDA submission.

Moreover plaintiffs' allegations raise a strong inference of scienter. All defendants are alleged to have disseminated or approved these statements that they knew to be false. *See id.* ¶ ¶ 20, 67-68. Defendant Goldstein is designated a contact person in the press release itself. Defendant Henkel, as noted above, allegedly "knew that the day 14 post-treatment endpoint was an important endpoint for determination of efficacy" and also knew that there was *"no standard practice for the use of follow-up prophylactic therapy in the treatment of esophageal candidiasis." Id.* ¶ 39 (emphasis in original). Again, anidulafungin was the company's lead product in development and "the first of three promising advanced stage product candidates [Vicuron] [was] working to commercialize around the world ..." *See* Jan. 6, 2003 Press Release. The importance of anidulafungin to Vicuron supports at the very least a strong inference of recklessness on the part of the defendant officers and directors of Vicuron as to these alleged misrepresentations. *Advanta,* 180 F.3d at 539.

*7 The pleading standards under Rule 9(b) and the PSLRA are clearly met.

3. March 17, 2003 Conference Call

Officer defendants Horner, Goldstein, and Henkel [FN21] held a conference call on March 17, 2003 with investment analysts concerning the March 17, 2003

press release and Vicuron's Phase III study of anidulafungin. [FN22] Henkel made assurances in response to inquiries about the two-week post-treatment endpoint by stating that it was simply the standard for any "infected clinical trials" and that Vicuron's trial had been more stringent. He also stated that more patients being treated with retroviral therapy during the Phase III study may have impacted the relapse rate results. Based on these statements, the plaintiffs allege, "the market did not conclude that the Phase III study was in serious jeopardy because of the inferior two week post-treatment endpoint relapse rate data for anidulafungin." *Id.* ¶ 40. The amended complaint asserts that defendants' misrepresentations regarding the unimportance of the relapse rates and the "confounded efficacy data in the Phase III study" with regard to retroviral therapy operated to conceal their knowledge that anidulafungin lacked any competitive advantage over existing therapies. *Id.* ¶ 41.

FN21. *See supra* footnote 2.

FN22. *March 17, 2003 Conference Call:* (as excerpted by plaintiffs, in relevant part)
Joel Sendek-Analyst-Lazard Freres & Co: Thanks, couple of questions on I guess first on trial design. You measure the primary endpoint on last day of treatment or after the seven day symptom free period?
Tim Henkel-Versicor [Vicuron]-EVP/CMO: Primary endpoint is measured at end of therapy, *just at the last day of treatment.*
Joel Sendek-Analyst-Lazard Freres & Co: Last day of treatment. Okay. As far as the secondary endpoint is concerned, you know *if its [sic] not clinically relevant or whatever I was just wonder [sic] why you measure it.*
Tim Henkel-Versicor [Vicuron]-EVP/CMO: First of all there are multiple secondary endpoints; the most important is clinical and mycological responses at the end of therapy. *We also measure the endpoint at the follow-up visit largely because it is the standard for any infected clinical trials, typically done for this.* However, I should add *our trial was somewhat more stringent* if we looked at endoscopic responses at follow-up when many of the studies have only looked at clinical signs and symptoms at follow-up. But we have a more sensitive measure of early recurrence than most studies in the disease do.
Tom Shrader-Analyst-Gerard Klauer Mattison: Hi guys, I have a question *on the secondary endpoint.* I understand your argument that *it is not relevant.* My first question is Candidiasis [Cancidas?] saw exactly the same thing. Why is that? I mean, this supposed to be a sidle [superior?] drug. I understand it may not mean anything, but I expect the results to be the opposite way. Do you have any idea what is going on?
Tim Henkel-Versicor [Vicuron]-EVP/CMO: I can speculate a bit, Tom. But, the short answer is we really don't know why. One thing we are pointing out about our study, while the patient populations are very well balanced with regard to most parameters, *we did have more patients in the Fluconazole arm and our study on retroviral therapy could have had an impact.* We have seen this for Candidiasis [Cancidas?] as you pointed out. We have had internal discussions and discussions with a few outside experts recently. We can speculate about slight differences in tissue penetration into relatively protected sites in the oral [pharynx] for example where Fluconazole might have a slight advantage in a [radication] but it really is all speculations. *The important thing is to point out how high the rates are.* It is hard to get better than that.

These conference call statements, as with the related press release, contain material information and are alleged to have misled the market. They are not forward-looking. Both segments identified in the amended complaint discuss almost exclusively the results of the Phase III clinical trial.

There also is a strong inference of scienter as to Horner, Goldstein, and Henkel. They had special roles and responsibilities in communicating information to the investment community. Am. Compl. ¶ 12. As stated above, anidulafungin was Vicuron's lead product in development, and its importance to the company supports at least a strong inference of recklessness of all the company's officers and directors named as defendants. *Advanta,* 180 F.3d at 539.

Again, the pleading requirements under Rule 9(b) and the PSLRA are satisfied.

4. April 28, 2003 Press Release

Portions of Vicuron's April 28, 2003 press release [FN23] are also claimed to be materially false or misleading. Plaintiffs assert that defendants knew that their Phase III study had weakened the chances for FDA approval of anidulafungin, but that defendants made the NDA filing and false statements about it despite their purported knowledge and concealment of these serious Phase III problems. Plaintiffs also maintain that the comparisons between anidulafungin and fluconazole based on the Phase III study were hopelessly confounded because some of the persons studied were on retroviral therapy. Am. Compl. ¶ 44.

FN23. *April 28, 2003 Press Release:* (as excerpted by plaintiffs)
Vicuron Pharmaceuticals Inc. today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for anidulafungin, a novel antifungal agent for the treatment of EC, a painful and debilitating infection of the esophagus that commonly affects patients with compromised immune systems. Anidulafungin belongs to the first new class of antifungal agents, called echinocandins, introduced in more than 40 years.
"This is the most important corporate milestone achievement in our relatively brief history, and our development team has done an excellent job executing this filing expeditiously," said George F. Horner III, president and CEO of Vicuron. "Echinocandins such as anidulafungin promise to revolutionize the treatment of fungal infections, and represent a growing market opportunity in the United States and Europe. Drugs in this class are distinct due to their fungicidal activity, ability to treat a broad range of fungi, low potential for development of resistance and favorable side effect profile. Anidulafungin is further distinguished by its quicker achievement of steady state, strong in vitro potency, ability to be given at high doses and favorable drug interaction profile. We believe anidulafungin promises to become an important treatment for serious fungal infections and that these attributes should enable us to position it competitively within the new echinocandin class."
Vicuron's request for marketing clearance is based largely on the results of a pivotal Phase III trial that statistically showed intravenous anidulafungin is as effective as oral fluconazole, the current standard-of-care, in treating EC. Based on results from this study, anidulafungin is well-tolerated with an adverse event and laboratory safety profile comparable to oral fluconazole. The file also includes safety and efficacy data from a large Phase II study with anidulafungin in invasive candidemia/candidiasis, as well as safety data from a Phase III trial studying anidulafungin in combination with a liposomal amphotericin for the treatment of invasive aspergillosis and a number of additional Phase I and Phase II clinical trials.
"The pivotal Phase III results in addition to positive data from our Phase II trial studying anidulafungin in invasive candidiasis and candidemia, a life-threatening fungal infection, form the basis of what we believe is a strong NDA submission," said Timothy J. Henkel, M.D., Ph.D., Vicuron's chief medical officer. "We look forward to working with the FDA to process this application as efficiently and quickly as possible. We plan to file for registration in Europe and Canada in the second half of this year."
Vicuron will present Phase II data with anidulafungin in invasive candidemia/candidiasis, the most common hospital-based fungal infection, at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) conference in the United Kingdom in May.
With the aging population and the growing number of immunocompromised patients, serious hospital-based fungal infections represent a large and growing market opportunity. *The worldwide market for echinocandins is estimated to be $1.8 billion by the year 2008, according to Datamonitor.*
(Emphasis in original.)

Finally, plaintiffs aver that defendants' concealment of the Phase III study results, their misrepresentation of the standard of care for EC, and their knowledge of different in vivo properties of anidulafungin versus the drug caspofungin show that defendants knew anidulafungin lacked any competitive advantage over caspofungin in the treatment of EC. *Id.* ¶ 45. Thus, anidulafungin lacked the competitive advantages

necessary to share in the "worldwide market for echinocandins ... estimated to be $1.8 billion by the year 2008." *Id.*

***8** First, we find that the statements outlined in this press release cannot be dismissed as immaterial. Nevertheless, the following portion identified in the amended complaint is a protected forward-looking statement: "The worldwide market for echinocandins is estimated to be $1.8 billion by the year 2008, according to Datamonitor." This press release is accompanied by cautionary language, and actual knowledge of falsity with regard to this portion is not alleged. Thus, this prediction falls within the safe harbor of the PSLRA.

However, the other two highlighted portions discuss the results of the Phase III study and are not forward-looking. Further, as to scienter, plaintiffs have alleged that defendants "knew the Phase III study failed to generate any data pointing to the competitive advantages of anidulafungin over fluconazole." *Id.* ¶ 44. The pleadings meet the requirements of Rule 9(b) and the PSLRA and raise a "strong inference" of scienter. *See also id.* ¶ ¶ 20, 67-68. Again, we note that anidulafungin was Vicuron's lead product in development, which in itself supports a finding of scienter for alleged misrepresentations as to it. *Advanta*, 180 F.3d at 539.

We agree with plaintiffs, except as noted above, that they have met the pleading requirements under Rule 9(b) and the PSLRA.

5. July 17, 2003 Prospectus and July 18, 2003 Registration Statement incorporating the 2002 Form 10-K

Plaintiffs contend that the Prospectus [FN24] and Registration Statement [FN25] filed with the SEC in July, 2003 contained false statements because they claimed "competitive advantages" of anidulafungin.

FN24. *Prospectus:*
Our lead antifungal product candidate, anidulafungin, is intended for the intravenous treatment of serious systematic fungal infections. Anidulafungin has potent activity against the principal yeasts, such as Candida, and molds, such as Aspergillus, that cause serious fungal infections. In addition, anidulafungin has fungicidal activity, which means that it kills the fungus. This is in contrast to many widely-used antifungal agents which only inhibit fungal growth. Because of anidulafungin's novel mechanism of action, it is active against strains resistant to other agents, such as fluconazole. We believe anidulafungin will have competitive advantages over existing therapies because it combines potent fungicidal activity with a good resistance profile to date. In early 2003, we completed a Phase III clinical trial with anidulafungin for the treatment of esophageal candidiasis. Based in part on the results of that trial, in April 2003, we filed a NDA for anidulafungin for the treatment of invasive candidiasis/candidemia and based on positive results from this trial, recently began a Phase III clinical trial to evaluate anidulafungin in combination with liposomal amphotericin for the potential treatment of invasive aspergillosis. (Emphasis added).

FN25. *Registration Statement-2002 Form 10-K:*
Anidulafungin. Our lead antifungal product candidate, anidulafungin, is intended for the intravenous treatment of serious systemic fungal infections. Anidulafungin has potent activity against the principal yeasts, such as Candida, and molds, such as Aspergillus, that cause serious fungal infections. In addition, anidulafungin has fungicidal activity, which means that it kills the fungus. This is in contrast to many widely-used antifungal agents which only inhibit fungal growth. Because of anidulafungin's novel mechanism of action, it is active against strains resistant to other agents, such as fluconazole. We believe anidulafungin will have competitive advantages over existing therapies because it combines potent fungicidal activity with a good resistance profile to date. (Emphasis added).

The statements in the Prospectus and the Registration Statement incorporating the 2002 Form 10-K concerning competitive advantages of anidulafungin are based on claims of its potency and resistance profile. The Prospectus also discusses the Phase III results as a basis for Vicuron's submission of its NDA to the FDA. These statements are material and are not forward-looking. As we have discussed with regard to previous statements, scienter is alleged as to the potency and Phase III claims. Anidulafungin was

Vicuron's lead product in development, and its importance to the company supports at least a strong inference of recklessness of the defendants. *Advanta*, 180 F.3d at 539.

We note the amended complaint has properly pleaded this claim.

6. December 11, 2003 Healthcare Conference

Plaintiffs claim that defendant Goldstein, Vicuron's Chief Financial Officer, made materially false and misleading statements to the investment community during his presentation on December 11, 2003 at the Harris Nesbitt Gerard Healthcare Conference. [FN26]

FN26. *December 11, 2003 Healthcare Conference* (as excerpted by plaintiffs)
Let me give you a quick overview of Vicuron and why we think this is a very interesting proposition for investors. As Tom mentioned, we're very fortunate to have global rights to two late-stage products. Anidulafungin, our lead product, which is an antifungal agent we've filed with the FDA. Our PDUFA date is February 25th of 2004. And dalbavancin, which is an injectable antibiotic. And I will tell you a lot more about both those drugs and their potential.
So let me tell you a little bit about anidulafungin, the lead product. Anidulafungin is a member of a new class of antifungals called echinocandins. This is the first new class of antifungals we have had in 40 years.
Let me show you a little bit about Caspofungin sales. This really shows you-this is the Caspofungin quarterly sales on a worldwide basis for the last two years, and what you see here is that the sales are really taking off. The last quarter, they did 77 million in sales, so a little over $300 million run rate, still growing very rapidly. *And to give you a sense, our consensus analysts' estimates have anidulafungin as about a $250 million worldwide opportunity. So even though we feel we have got a much better compound, we don't have to beat Merck in the marketplace and still do very well for investors.*
Let me walk you through the pivotal study for our file. This is an esophageal candidiasis study, 600-patient study, largest study ever conducted in this disease process. *Primary endpoint is endoscopic response at end of IV therapy.* And I'm sorry after lunch to show this to you-sort of graphic photos, looking down the esophagus. On your left-hand side, you see these ugly white plaques, and an aftertreatment with anidulafungin, clean plaques. That is what we're measuring. Anidulafungin performed extremely well, a 97.2 percent response rate versus fluconazole, 98.8(ph) percent. As with all anti-infective studies, non-inferiority study design. And what is important here is the 95 percent confidence interval runs from -4.1 percent to 0.8 percent, so it shows you that those two numbers are statistically equivalent, and also at a very tight confidence interval of -4.1 percent versus the agreed-upon so-called delta at -10 percent. Also critically important are the side effects seen in the study, a 9.3 percent drug-related adverse events for anidulafungin versus fluconazole 12 percent. So clean and clean against a very clean drug, fluconazole.
Let me step back. We have talked a little bit about the dosing of anidulafungin, *the ability to give more dose, 200-milligram loading over 100-milligram maintenance dose for serious infections. We also have an intrinsically more potent drug, about tenfold more potent in vitro than Caspofungin. We have a drug that has a longer half-life, about 24 hours versus 12 hours for Caspofungin.* But I am going to walk you through the drug interaction (ph) profile for our drug and special populations profile, and a unique mechanism of the elimination for our drug.
So if you look here, this is area under the curve for anidulafungin, and what you see here is that you have no change with area under the curve, whether you have a p450 inhibitor, a p450 inducer, or Rifampin, the classic p450 inducer, an important TB medication. *In contrast, if you look at the Merck compound, which goes through p450 metabolism,* you have got a dose adjust for refantin, and there's some label warnings for HIV medications. This is critically important, because I see patients who are often on 10 or more medications.
If you look at what happens when we have dysfunction of the renal system or hepatic system, the classic elimination pathways,

> again, no change of area under the curve. And let me tell you, in contrast to Merck, you have got a dose adjust for hepatic impairment.
> And that, of course, begs the question why do we have these benefits that you don't see with other compounds? (Inaudible) the schematic of the classic drug elimination pathways. It's either renal excretion or hepatic metabolism. In the world of antifungals, most of the action is in hepatic metabolism. *Caspofungin, Micafungin and the azoles go through hepatic metabolism, therefore compete with the p450 system.* Also, if you have got hepatic dysfunction, you don't have elimination of the drugs well, so you have got to dose adjust for patients with hepatic dysfunction. Anidulafungin has a truly unique elimination pathway; it spontaneously breaks down in blood and tissue non-enzymatically, and therefore it is not at all reliant on the hepatic system.
> So to quickly walk you through the advantages of our drug, rapidly achieves steady-state. I have not shown you the data, but a single dose gets you to steady-state for anidulafungin versus two weeks of therapy with Caspofungin. Rapidly and extensively distributes to tissue. *It has got a volume of distribution three times the volume of distribution of Caspofungin and Micafungin.* Very favorable drug interaction profile we have talked about. No dose adjustments for compromised systems, and this unique elimination pathway.
> Quickly, through the financials, we are in good cash position-$173 million at the end of the third quarter of this year. *We did a very successful follow-on offering, which Harris Nesbitt helped us do in July.* This is our milestones, and this, again, is really one of the cornerstones of the business, of our business and the value proposition. What we do, sort of as an internal and external scorecard, is at the J.P. Morgan conference at the beginning of the year, we put out these milestones (technical difficulty) changed them, and we grade ourselves accordingly. Let me walk through how we have done this year, and give you a snapshot of the first half of 2004. *We successfully presented positive Phase III data for esophageal candidiasis; we filed the NDA on time in April. We're planning to file in Europe, as part of our initial function in Europe, as part of our goal to commercialize the agent in the big five countries in Europe. We are on track to do that before the end of this year. And the timeline has FDA approval in a PDUFA date of February 25th of 2004 and product launch in Q2 of next year.*
> (Emphasis in original.)

Although Goldstein allegedly knew anidulafungin would have less favorable in vivo results than Merck's drug caspofungin, he estimated $250 million in future annual anidulafungin sales and represented that anidulafungin was superior to caspofungin. Amended Compl. ¶ 52. Plaintiffs also complain that Goldstein made claims in the conference that anidulafungin was more potent than caspofungin, even though equal doses had been used in the Phase III trials and the in vitro comparison of potency was not clinically relevant. Further, as studies purportedly had found no significant difference between the relapse rates of caspofungin and fluconazole, plaintiffs aver that the inferior relapse rates of anidulafungin to fluconazole made it inferior to both those other drugs. *Id.* ¶ 55. Goldstein did not reveal this fact. *Id.* Finally, according to the amended complaint, the repeated claim that caspofungin "goes through p450 metabolism" was "blatantly false and misleading because caspofungin does not rely on p450 metabolism for its elimination from the body, nor does it inhibit p450 metabolism." *Id.* ¶ 56.

***9** We find that all of the statements made at the Healthcare Conference identified by plaintiffs to be material, as they cover specific comparisons between anidulafungin and other drugs, the primary endpoint, and the NDA filing.

The first statement highlighted by plaintiffs reads: "And to give you a sense, our consensus analysts' estimates have anidulafungin as about a $250 million worldwide opportunity. So even though we feel we have got a much better compound, we don't have to beat Merck in the marketplace and still do very well for investors." As we have mentioned, plaintiffs have alleged that caspofungin, Merck's product, had statistically the same relapse rates as fluconazole, but that anidulafungin had statistically worse relapse rates than fluconazole. Thus, plaintiffs claim there is no basis upon which defendants could have truthfully made this claim and that it was made recklessly. Plaintiffs have adequately pleaded scienter, and the safe harbor for forward-looking statements is not satisfied here.

The following statement, however, is too vague to be

actionable:
We're planning to file in Europe, as part of our initial function in Europe, as part of our goal to commercialize the agent in the big five countries in Europe. We are on track to do that before the end of this year.

This statement is not specifically alleged to be false, and no actual knowledge that it is false is alleged by plaintiffs. It is largely puffery. *Advanta*, 180 F.3d at 538.

Nevertheless, defendants allegedly had no basis to believe that FDA approval would occur, as they were aware of the shortcomings of anidulafungin. Hence, the following portion cannot fall under the safe harbor for forward-looking statements because it was recklessly made:
We successfully presented positive Phase III data for esophageal candidiasis; we filed the NDA on time in April.... And the timeline has FDA approval in a PDUFA date of February 25th of 2004 and product launch in Q2 of next year.

Further, scienter is alleged as to this portion for the same reason.

None of the following statements is forward-looking, as they address established specifics of anidulafungin and its evaluation and performance relative to other drugs:
• Primary endpoint is endoscopic response at end of IV therapy.
• We have talked a little bit about the dosing of anidulafungin, the ability to give more dose, 200-milligram loading over 100-milligram maintenance dose for serious infections. We also have an intrinsically more potent drug, about tenfold more potent in vitro than Caspofungin. We have a drug that has a longer half-life, about 24 hours versus 12 hours for Caspofungin.
• In contrast, if you look at the Merck compound, which goes through p450 metabolism, you have got a dose adjust for refantin, and there's some label warnings for HIV medications.
• Caspofungin, Micafungin and the azoles go through hepatic metabolism, therefore compete with the p450 system.
***10** • It has got a volume of distribution three times the volume of distribution of Caspofungin and Micafungin.

Plaintiffs have alleged actual knowledge that Goldstein's representations regarding endpoints were false and misleading, because he knew the relapse rates measured at two weeks post-treatment were important to FDA approval. Am. Compl. ¶ 54. Plaintiffs allege Goldstein knew and concealed the different properties of anidulafungin and caspofungin. The statements about the p450 metabolism are alleged to be "blatantly false and misleading." The statement in the press release that anidulafungin had a significantly greater volume of distribution [FN27] than caspofungin is alleged to be false because these two drugs at best were of equal potency based on Vicuron's Phase III study. *Id.* ¶ 53. Defendant Goldstein, Chief Financial Officer, allegedly had actual knowledge of the different properties of the two drugs. Goldstein's duties described in the amended complaint involved communicating to the investment community. *Id.* ¶ 12. Further, the amended complaint alleges he studied the marketplace and was familiar with anidulafungin and related drugs and that data was concealed and/or not disclosed. *Id.* ¶ 20. Aside from the fact that anidulafungin was the company's lead product in development, Goldstein is specifically alleged to have known non-public information about the drug, the NDA, and the clinical studies. *Id.* ¶ 12. As the scienter requirement is met, we will not dismiss claims arising from these statements made in the Healthcare Conference.

FN27. As we understand from the materials provided, "volume of distribution" refers to attaining a uniform concentration of a drug in the relevant tissue of the body.

The statement "[w]e did a very successful follow-on [sic] offering, which Harris Nesbitt helped us do in July," is not forward-looking, but plaintiffs do not state with particularity that it was false or misleading. Thus, claims arising from this statement is not actionable.

Except as noted above, defendants' argument that plaintiffs have not properly pleaded this claim is without merit.

7. March 15, 2004-2003 Form 10-K

Finally, plaintiffs maintain that defendants' 2003 Form 10-K [FN28] filed with the SEC contained statements that were materially false and misleading. The amended complaint alleges that the defendants' claims about the competitive advantages of anidulafungin were unfounded. For the same reasons

as we have stated above with regard to the 2002 Form 10-K, we find the statement to be material and not forward-looking. The plaintiffs have pleaded with particularity that defendants knowingly or recklessly made the allegedly false statement about the potency of anidulafungin and results of the Phase III study. Moreover, as anidulafungin was the company's lead product in development, its importance to the company supports at least a strong inference of recklessness of all the company's officers and directors named as defendants. *See* Advanta, 180 F.3d at 539.

> FN28. *2003 Form 10-K* (as excerpted by plaintiffs)
> Our lead antifungal product candidate, anidulafungin, is intended for the intravenous treatment of serious fungal infections. Anidulafungin has potent activity against the principal yeasts, such as Candida, and molds, such as Asperigillus, that cause serious fungal infections. In addition, anidulafungin has fungicidal activity, which means that it kills the fungus. This is in contrast to many widely-used antifungal agents which only inhibit fungal growth. Because of anidulafungin's different mechanism of action, it is active against strains resistant to other agents, such as fluconazole. *We believe anidulafungin will have competitive advantages over existing therapies because it combines potent fungicidal activity with a good resistance profile to date.* In early 2003, we completed a Phase III clinical trial with anidulafungin for the treatment of esophageal candidiasis. Based in part on the results of that trial, in April 2003, we filed an NDA for anidulafungin for the treatment of esophageal candidiasis, which was accepted for review by the FDA in June 2003. In January 2004, we announced that we received notification from the FDA that it now anticipates completing its review of our anidulafungin NDA on May 25, 2004, which represents a 90-day extension of the original action date. The extension was triggered by the FDA's request for additional pharmacokinetic data. *We continue to expect the launch of anidulafungin in the first half of 2003 as planned,* although our plans are dependent on receiving FDA approval.

Again, all pleading requirements have been satisfied.

B. Loss Causation

***11** Defendants seek to dismiss plaintiffs' claim under Rule 10b-5 on the basis that plaintiffs failed properly to plead loss causation, that is, the causal connection between the alleged misrepresentation and their loss. Under Rule 10b-5, a plaintiff must plead and prove "that he or she suffered an actual economic loss," and specifically that "the alleged misrepresentations proximately caused the decline in the security's value." Semerenko v. Cendant Corp., 223 F.3d 165, 185 (3d Cir.2000). *See also* Dura Pharm., ---U.S. ----, 125 S.Ct. 1627, 161 L.Ed.2d 577. Purchase of a security at a price that is artificially inflated due to an alleged misrepresentation and a loss therefrom constitutes "a sufficient causal nexus between the loss and the alleged misrepresentation to satisfy the loss causation requirement." *Semerenko,* 233 F.3d at 184. The artificial inflation must actually be "lost" due to the alleged fraud. Semerenko, 223 F.3d at 185. Artificial inflation itself is not enough. Dura Pharm., 125 S.Ct. at 1631.

Here, plaintiffs specifically allege that defendants' misrepresentations about the relapse rates and effectiveness of anidulafungin caused the market price of Vicuron common stock to become "artificially inflated during the Class Period." Am. Compl. ¶ 3. *See also id.* ¶ ¶ 4, 8. The amended complaint cites a Reuters news report of May 24, 2004, which includes the comments of defendant Goldstein, Chief Financial Officer of Vicuron, discussing the FDA's refusal to approve the NDA and relapse rates of anidulafungin. It alleges that "[a]s a result of the partial disclosure by the Company of the FDA letter, including the shocking news regarding the lack of support for a label claim for EC, the price of Vicuron plummeted." *Id.* ¶ ¶ 60-61. Plaintiffs assert "[w]hen investors were informed of the implications of the 'approvable letter', the true impact of the relapse rate data and the unproven superiority of anidulafungin in the treatment of refractory disease, the market price of Vicuron stock collapsed." *Id.* ¶ 8. The amended complaint also specifically states that plaintiffs and other members of the Class were deceived and caused to "purchase Vicuron securities at inflated prices and to sustain damages." *Id.* ¶ 17.

Thus, loss causation has been adequately pleaded.

IV.

Defendants move to dismiss claims brought under § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against the officer defendants Horner, Goldstein, and Henkel. [FN29] This statutory provision imposes joint and several liability on any person "who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder ... unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a). To plead a violation of § 20(a), plaintiffs must state facts showing an underlying violation by the company and the circumstances establishing the defendant's control over the company's actions. *See Winer Family Trust v. Queen*, No. 03-4318, 2004 WL 2203709, *22 (E.D.Pa. Sept.27, 2004); *La Fata v. Raytheon Co.*, 207 F.R.D. 35, 45 n. 5 (E.D.Pa.2002). Section 20(a) claims are not subject to the heightened pleading requirements of Rule 9(b). *Winer Family Trust*, 2004 WL 2203709, *22.

FN29. *See supra* footnote 2.

***12** Relying on their arguments to dismiss plaintiffs' claim for violations of § 10(b) of the Exchange Act, defendants maintain that the § 20(a) claim cannot stand because there were no § 10(b) violations. For the purposes of this motion to dismiss, however, and based on the court's determination that plaintiffs properly have pleaded claims under § 10(b), we will deny defendants' motion to dismiss the claims under § 20(a).

V.

Finally, defendants move to dismiss claims brought against the director defendants [FN30] under § 11 of the Securities Act, 15 U.S.C. § 77k. Liability under § 11 of the attaches to those who sign a registration statement if "any part" of it "contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). Therefore, plaintiffs must plead that they bought the security and that there was a material misstatement or omission. *Herman & MacLean v. Huddleston*, 459 U.S. 375, 381-82, 103 S.Ct. 683, 74 L.Ed.2d 548 (1983). Even innocent misstatements may give rise to liability, as liability is "virtually absolute." *Id.* at 382. The director defendants are alleged to have signed the Registration Statement for the July 18, 2003 offering, which purportedly contained false statements. Am. Compl. ¶ ¶ 76-79.

FN30. *See supra* footnote 2.

Defendants argue that the § 11 claim should be dismissed because it does not meet the Rule 9(b) pleading standards. However, plaintiffs have drafted this claim without reference to any mental state. While the amended complaint specifically incorporates the foregoing paragraphs into the § 11 claim, it also reads: "Plaintiffs for the purposes of this claim, disclaim any allegations of fraud." *Id.* ¶ 75. Plaintiffs are therefore not be held to the heightened pleading requirement of Rule 9(b) of the Federal Rules of Civil Procedure as to this claim. *See In re Ravisent Techs., Inc.*, No. CIV.A. 00-CV-1014, 2004 WL 1563024, *13 (E.D.Pa. July 13, 2004). Construing all reasonable inferences in the light most favorable to plaintiffs, we find they have stated a claim under § 11.

VI.

In summary, we will deny plaintiffs' motion to strike exhibits in support of defendants' motion to dismiss plaintiffs' amended complaint. We will deny defendants' motion to dismiss the complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, in accordance with the above analysis.

(Emphasis in original.)

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Briefs and Other Related Documents (Back to top)

- 2005 WL 2150098 (Trial Pleading) Defendants' Answer to Amended Complaint (Aug. 01, 2005)
- 2004 WL 2695522 (Trial Motion, Memorandum and Affidavit) Memorandum in Further Support of the Institutional Investor Group's Motion for Appointment as Lead Plaintiff and Approval of Selection of Lead and Liaison Counsel and in Reply to the Oppositions of the Other Movants (Sep. 15, 2004)
- 2004 WL 2695531 (Trial Motion, Memorandum and Affidavit) Reply Memorandum of Law in Further Support of the Motion to Appoint the Vasquez Group as Lead Plaintiff and for Approval of its Selection of Lead Counsel (Sep. 15, 2004)
- 2004 WL 2695494 (Trial Motion, Memorandum and Affidavit) Memorandum in Further Support of the Motion of the Institutional Investor Group for Appointment as Lead Plaintiff and for Approval of Selection of Lead and Liaison Counsel and in Opposition to the Competing Motions (Sep. 02, 2004)
- 2004 WL 2696118 (Trial Motion, Memorandum and Affidavit) Response to Competing Lead Plaintiff Motions (Aug. 30, 2004)
- 2004 WL 2695475 (Trial Pleading) Complaint For Violation of The Federal Securities Laws (Jun. 15, 2004)
- 2:04cv02627 (Docket) (Jun. 15, 2004)

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